

REMARKS

Specification Amendments

The specification has been amended at page 3, line 24, to add three sentences directed to NPAR agonists that are thrombin peptide derivatives described in U.S. Patent Nos. 5,352,664 and 5,500,412, such as thrombin peptide derivatives comprising a thrombin receptor binding domain having the L-amino acid sequence Arg-Gly-Asp-Ala (SEQ ID NO: 7); and a serine esterase conserved sequence. Support for the three added sentences is found in the specification, for example, at page 3, line 20, which incorporates by reference the entire contents of U.S. Patent Nos. 5,352,664 and 5,500,412. The added sentences are taken from both patents, for example, see column 4, lines 12-28 of U.S. Patent No. 5,352,664 and column 4, lines 2-17 of U.S. Patent No. 5,500,412.

The specification has also been amended to add two paragraphs at page 4, line 27, to recite definitions for the phrases "thrombin receptor binding domain" and "serine esterase conserved sequence." Support for the two added paragraphs is found in the specification, for example, at page 3, line 20, which incorporates by reference the entire contents of U.S. Patent Nos. 5,352,664 and 5,500,412. This two-paragraph portion is identically recited in both patents and is contained at column 6, line 66-68, continuing to column 7, lines 1-10, of U.S. Patent No. 5,352,664, and at column 6, lines 45-55, of U.S. Patent No. 5,500,412.

The specification has also been amended to correct a typographical error in the paragraph at page 9, line 22 to page 10, line 9.

No new matter has been added by these amendments to the specification.

Substitute Sequence Listing

Transmitted concurrently herewith is a copy of a Substitute "Sequence Listing" in paper form (sheets 1/4 through 4/4) comprising SEQ ID NOs: 1 through 9 for the above-identified patent application as required by 37 C.F.R. §§ 1.825(a) and 1.821(c), and a copy of the Substitute

"Sequence Listing" in computer readable form as required by 37 C.F.R. §§ 1.825(b) and 1.821(e). Please replace the "Sequence Listing" mailed to the Patent Office on June 1, 2004 (sheets 1/3 through 3/3) with the attached Substitute "Sequence Listing" (sheets 1/4 through 4/4).

The Substitute "Sequence Listing" filed concurrently herewith adds SEQ ID NO: 7, the amino acid sequence Arg-Gly-Asp-Ala. Support for SEQ ID NO: 7, which corresponds to the amino acid sequence for the thrombin receptor binding domain, is found in the specification as originally filed, for example, at page 3, line 20, which incorporates by reference the entire contents of U.S. Patent Nos. 5,352,664 and 5,500,412. This amino acid sequence (SEQ ID NO: 7) is identically recited in both patents and is contained, for example, at column 4, lines 25-26, of U.S. Patent No. 5,352,664, and at column 4, lines 13-15, of U.S. Patent No. 5,500,412.

The Substitute "Sequence Listing" filed concurrently herewith also adds SEQ ID NO: 8, the amino acid sequence Asp-Ala-Cys-Glu-Gly-Asp-Ser-Gly-Gly-Pro-Phe-Val. Support for SEQ ID NO: 8, which corresponds to the amino acid sequence for a serine esterase conserved sequence, is found in the specification as originally filed, for example, at page 3, line 20, which incorporates by reference the entire contents of U.S. Patent Nos. 5,352,664 and 5,500,412. This amino acid sequence (SEQ ID NO: 8) is identically recited in both patents and is contained, for example, at column 4, lines 27-28, of U.S. Patent No. 5,352,664, and at column 4, lines 15-17, of U.S. Patent No. 5,500,412.

The Substitute "Sequence Listing" filed concurrently herewith further adds SEQ ID NO: 9, which consists of the amino acid sequence Asp-X₁-Cys-X₂-Gly-Asp-Ser-Gly-Gly-Pro-X₃-Val, wherein X₁ is either Ala or Ser; X₂ is either Glu or Gln; and X₃ is either Phe, Met, Leu, His, or Val. Support for SEQ ID NO: 9, which corresponds to the amino acid sequence for a serine esterase conserved sequence, is found in the specification as originally filed, for example, at page 3, line 20, which incorporates by reference the entire contents of U.S. Patent Nos. 5,352,664 and 5,500,412. This amino acid sequence (SEQ ID NO: 9) is identically recited in both patents and is contained, for example, at column 7, lines 7-10, of U.S. Patent No. 5,352,664, and at column 6, lines 52-55, of U.S. Patent No. 5,500,412.

As required by 37 C.F.R. § 1.825(b), Applicant's Attorney hereby states that the contents of the Substitute "Sequence Listing" in paper form and in the computer readable form submitted herewith are the same and, as required by 37 C.F.R. § 1.825(a), also states that the submission includes no new matter.

Claim Amendments

Claims 27 and 29-33 have been canceled. Claims 1-3, 5, 8, 11, 14, 17, 18, 21, 22 and 34 have been amended to clarify their meaning.

New Claims 35-42

The subject matter of new Claims 35-42 is fully supported in the present application as originally filed. Support can be found in the specification, for example, at page 3, line 20, which incorporates by reference the entire contents of U.S. Patent Nos. 5,352,664 and 5,500,412; in the three sentences added at page 3, line 24; in the two paragraphs added at page 4, line 27; at page 4, lines 1-12; and at page 9, lines 1-6. No new matter is added by the new claims.

Traversal of Restriction Requirement

Applicant respectfully traverses the restriction requirement. The restriction requirement is unconventional and difficult to understand. The Examiner states on page 3, first full paragraph of the Office Communication mailed from the US Patent and Trademark Office on 20 October 2004, "The applicant should be aware that selection of a single SEQ ID NO: represents a response to a restriction requirement, not an election of species." Restriction Requirements are made when groups of claims to inventions are found to be either independent or distinct. The Examiner has not set forth any groups of claims to independent or distinct inventions. The Manual of Patent Examining Procedure states:

Every requirement to restrict has two aspects: (A) the reasons (as distinguished from the mere statement of conclusion) why the inventions *as claimed* are either independent or distinct; and (B) the reasons for insisting upon restriction therebetween as set forth in the following sections. (MPEP, 8th edition, revised May, 2004, section 808 entitled “Reasons for Insisting Upon Restriction”)

With respect to aspect (A), the Examiner has presented an analysis of the claims in terms of “peptide compounds” which have been assumed to be patentably distinct, because each one “is capable of eliciting a specific immune response and can be used to produce a specific antibody.” Applicant does not understand what reasoning connects the fact that different peptides can produce different immune responses, with the conclusion that claims to methods using peptides identified with different SEQ ID NOs represent distinct or independent inventions.

With respect to aspect (B), the Examiner has stated that, “Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, search, restriction for examination purposes as indicated is proper.” The Examiner has not reported any different classification for different groups of claims. In the parent application, International Application PCT/US02/01151, the subject matter was not found to lack unity of invention.

To formulate a search strategy, it should be noted that the peptides designated SEQ ID NOs 2-8 in the claims have similar structures, so that they would not all need to be searched individually. SEQ ID NOs 5 and 6 have the same amino acid sequence, but particular optional modifications of the termini have been designated, so that SEQ ID NO:5 and SEQ ID NO:6 are related as genus and species. SEQ ID NO:5 and SEQ ID NO:6 are both species of genus SEQ ID NO:2. SEQ ID NO:4 and SEQ ID NO:3 are related as genus and species. SEQ ID NO:9 and SEQ ID NO:8 are related as genus and species. SEQ ID NO:3 comprises the amino acid sequences of SEQ ID NO:5 and SEQ ID NO:6 within it.

In the absence of sufficient explanation of the restriction requirement, Applicant requests withdrawal of the requirement to select a single SEQ ID NO. Because of the similarities among

SEQ ID NOs 1-9, it would not present a burden to the Patent Office to search a reasonable number of SEQ ID NOs at one time.

Applicant also traverses the Examiner's requirement that Applicant elect a single disclosed moiety at positions R₁ and R₂. It would be unduly burdensome to require Applicant to individually prosecute every species within a genus comprising a method of treating skin ulcers using a peptide of a designated amino acid sequence. It should be recognized that searches based on the amino acid sequences of peptides will locate results describing peptides and polypeptides without regard to any modifications of the N- and C-termini. Applicant requests that this election of a single disclosed moiety at positions R₁ and R₂ be withdrawn, as search methods should make this unnecessary.

Respectfully submitted,

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